

# Cottage Food Administrative Rules of Montana (ARM) & Montana Codes Annotated (MCA)

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# Administrative Rules of Montana

## **37.110.501** PURPOSE

(1) The purpose of this subchapter is to provide rules in addition to the provisions stated in 50-50-102, 50-50-116, 50-50-117, and 50-50-121, MCA, so that cottage food products may be safely produced for the public in approved home kitchens.

## **37.110.502** DEFINITIONS

In addition to the definitions contained in 50-50-102, MCA, the following definitions apply to this subchapter:

- (1) "Baked goods" means breads, candies, cookies, pastries, and pies that are non-potentially hazardous because they are non-time temperature controlled for safety.
- (2) "Cottage food operator" means a person registered with the regulatory authority to operate a cottage food operation.
- (3) "Approved" means acceptable to the regulatory authority based on their determination of conformity with principles, practices, and generally recognized standards that protect public health.

#### **37.110.503** APPROVED COTTAGE FOOD PRODUCTS

- (1) Only those products approved by the department and listed in the registration may be produced by a cottage food operation. A cottage food operation is allowed to produce the following food items as long as they are a non-potentially hazardous food:
- (a) products that may be cooked in an oven including:
- (i) loaf breads, rolls, biscuits, quick breads, and muffins;
- (ii) cakes including celebration cakes such as birthday, anniversary, and wedding cakes;
- (iii) pastries and scones;
- (iv) cookies and bars:
- (v) crackers;
- (vi) cereals, trail mixes, and granola;
- (vii) pies, except that custard style pies, pies with fresh fruit that is unbaked, or pies that require refrigeration after baking are not approved;
- (viii) nuts and nut mixes; and
- (ix) snack mixes:
- (b) standardized jams, jellies, preserves, and fruit butters as identified under 21 CFR, Part 150, subject to the following:
- (i) fresh picked or harvested fruits from noncommercial sources are allowed for use;
- (ii) fresh fruits may be frozen in a household freezer and used at a later time;
- (iii) all recipes must have a cook step included such as a hot fill or hot water bath, and freezer or refrigerator-style products are not approved;
- (iv) all jams, jellies, preserves and fruit butters must be sealed in containers that are sterilized prior to filling; and
- (v) paraffin wax is not allowed for sealing;
- (c) repackaged, commercially dried fruit or vegetables from an approved source as described in ARM 37.110.510(2), or fresh fruits that:
- (i) have a natural pH below 4.6, specifically: apples, apricots, grapefruit, lemons, limes, mangos, nectarines, oranges, peaches, plums, pomegranates, tangerines, blackberries, blueberries, cherries, cranberries, currants, gooseberries, grapes, raspberries, strawberries, and huckleberries; and (ii) are dried by cottage food operators with the following methods:
- (A) during the fruit drying process the fruit must reach 160° Fahrenheit within an hour of processing the
- (B) the fruit must then maintain 140° Fahrenheit for the remainder of the drying process:
- (C) dried fruit may not be packaged using any method of reduced oxygen packaging, including vacuum packaging.
- (d) dry herb combining and packaging, and seasoning and mixture combining; examples of which are dry bean soup mixes, dry teas and coffees, and spice seasonings;
- (e) popcorn, popcorn balls, cotton candy;
- (f) fudge, candies, and confections that require a cook step;
- (g) molded chocolate using commercial chocolate melts; and
- (h) honey.
- (2) The following provisions apply to the production of cottage food products:
- (a) fresh picked or harvested fruits from noncommercial sources are allowed in baked good products;
- (b) fresh fruits can be frozen and used at a later time as long as there is a cook step in the recipe; and
- (c) all frostings or glazes must have a cook step or be made with ingredients (such as a large amount of sugar) that when combined are stable at room temperature.
- (3) Other products may be approved on a case-by-case basis by the department in consultation with the local health department of the county in which the cottage food operator is registered.



#### **37.110.504** LABELING

- (1) Cottage food operations must adhere to the labeling requirements outlined in 50-50-116, MCA.
- (2) The following is representative of a label meeting the requirements of (1):

# MADE IN A HOME KITCHEN THAT IS NOT SUBJECT TO RETAIL FOOD ESTABLISHMENT REGULATIONS OR INSPECTIONS

**Chocolate Chip Cookies** 

Net Wt. 8oz (227g)

Ingredients: Enriched flour (Wheat flour, niacin, reduced iron, thiamine, mononitrate, riboflavin and folic acid), butter (milk, salt), chocolate chips (sugar, chocolate liquor, cocoa butter, butterfat (milk), soy lecithin as an emulsifier), walnuts, sugar, eggs, salt, artificial vanilla extract, baking soda. Contains: Wheat, eggs, milk, soy, walnuts.

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- (3) The department may allow large cakes or a container of bulk products to be handled and labeled in the following manner:
- (a) be protected from contamination during transportation to the consumer; and
- (b) have a product label sheet with all the required information as listed in (1) that is provided to the consumer.

#### **37.110.506** COTTAGE FOOD OPERATOR HEALTH

- (1) Cottage food operators must not manufacture cottage food products (for example, working with exposed food; working with cleaning equipment, utensils, and linens; or working with unwrapped single-service or single-use articles) while experiencing the following symptoms:
- (a) vomiting;
- (b) diarrhea;
- (c) jaundice:
- (d) sore throat with fever;
- (e) a lesion containing pus such as a boil or infected wound that is open or draining and is:
- (i) on the hands or wrists, unless an impermeable cover such as a finger cot or stall protects the lesion and a single-use glove is worn over the impermeable cover;
- (ii) on exposed portions of the arms, unless the lesion is protected by an impermeable cover; or
- (iii) on other parts of the body, unless the lesion is covered by a dry, durable, tight-fitting bandage;
- (f) symptoms of any of the following illnesses as diagnosed by a health practitioner:
- (i) norovirus;
- (ii) hepatitis A virus;
- (iii) shigella spp.;
- (iv) shiga toxin-producing escherichia coli;
- (v) salmonella typhi; or
- (vi) nontyphoidal salmonella.
- (2) A cottage food operator experiencing persistent sneezing, coughing, or a runny nose that causes discharges from the eyes, nose, or mouth must not work with exposed food; clean equipment, utensils, and linens; or unwrapped single-service or single-use articles.

#### 37.110.507 PERSONAL CLEANLINESS

- (1) Cottage food operators must keep their hands and exposed portions of their arms clean.
- (2) Cottage food operators must use the following procedure in order to keep their hands and exposed portions of their arms clean:
- (a) rinse under clean, running warm water;



- (b) apply an amount of soap;
- (c) rub together vigorously for at least 10 to 15 seconds while:
- (i) paying particular attention to removing soil from underneath the fingernails during the cleaning procedure; and
- (ii) creating friction on the surfaces of the hands and arms or surrogate prosthetic devices for hands and arms, fingertips, and areas between the fingers;
- (d) thoroughly rinse under clean, running warm water; and
- (e) immediately follow the cleaning procedure with thorough drying using a single use towel.
- (3) Cottage food operators must clean their hands and exposed portions of their arms immediately before engaging in food preparation, which includes working with exposed food, clean equipment and utensils, and unwrapped single-service and single-use articles, and:
- (a) after touching bare human body parts other than clean hands and clean, exposed portions of arms;
- (b) after using the toilet room;
- (c) after caring for or handling service animals, household pets, or aquatic animals;
- (d) after coughing, sneezing, using a handkerchief or disposable tissue, using tobacco, eating, or drinking:
- (e) after handling soiled equipment or utensils;
- (f) during food preparation, as often as necessary to remove soil and contamination and to prevent cross contamination when changing tasks:
- (g) when switching between working with raw food and working with ready-to-eat food;
- (h) before donning gloves to initiate a task that involves working with food; or
- (i) after engaging in other activities that contaminate the hands.
- (4) Cottage food operators must keep their fingernails trimmed, filed, and maintained so the edges and surfaces are cleanable and not rough. Unless wearing intact gloves in good repair, a cottage food operator may not wear fingernail polish or artificial fingernails when working with unpackaged food.
- (5) Except for a plain ring such as a wedding band, cottage food operators may not wear jewelry on their arms and hands while preparing food, including medical information jewelry.
- (6) Cottage food operators must wear clean outer clothing to prevent contamination of food, equipment, utensils, linens, and single-service and single-use articles.

#### **37.110.508** HYGIENIC PRACTICES

- (1) A cottage food operator must not eat, drink, or use any form of tobacco in the registered area of the domestic residence while preparing a cottage food, or where the contamination of exposed food, clean equipment, utensils, and linens, unwrapped single-service and single-use articles, or other items needing protection can result.
- (2) Cottage food operators must provide a barrier between the registered area of their domestic residence and all pets while preparing and packaging cottage food items.

#### **37.110.510** MANUFACTURE OF COTTAGE FOOD PRODUCTS

- (1) Cottage food products must be safe, unadulterated, honestly presented, and:
- (a) must be offered for human consumption in a way that does not mislead or misinform the consumer;
- (b) food or color additives and colored overwraps may not be used to misrepresent the true quality of a cottage food product, although dying cookies or other similar products and/or wrapping them for a theme such as a green cookie for St. Patrick's Day or a popcorn ball wrapped in red plastic for Christmas is allowed.
- (2) Food must be obtained from approved sources, including:
- (a) retail and wholesale establishments licensed by the state of Montana;
- (b) fluid and dry milk products must:
- (i) be obtained pasteurized; and
- (ii) comply with grade A standards.
- (c) In many cases local farm products are considered approved sources; consult with your local health authority to make determinations on a case-by-case basis.
- (3) Eggs and dairy ingredients must be stored under refrigeration.
- (4) Upon receiving food packages from an approved source, food packages must be maintained in good condition and protect the integrity of the contents, so the food is not exposed to adulteration or potential contaminants.



- (5) Cottage food operators must minimize bare hand and arm contact with exposed food that is not in a ready-to-eat form.
- (6) Cottage food operators may not contact exposed, ready-to-eat food with their bare hands, and must use suitable utensils such as deli tissue, spatulas, tongs, single-use gloves, or dispensing equipment.
- (7) A cottage food operator may not use a utensil more than once to taste cottage food products or ingredients that are to be sold or served.
- (8) Food contact surfaces must be easily cleanable.
- (9) Food must only contact surfaces of equipment and utensils that are cleaned and sanitized as specified:
- (a) equipment food-contact surfaces and utensils must be clean to sight and touch;
- (b) food-contact surfaces of cooking equipment and pans must be kept free of encrusted grease deposits and other soil accumulations.
- (c) To the extent practicable, cottage food manufacturers should either dip utensils, dishes, and equipment in a 100 ppm chlorine bleach solution (or other approved sanitizer) and allow to air dry, or use the sanitizing cycle of a dishwasher.
- (10) Toxic chemicals such as household cleaners, concentrated bleach, and pesticides must be stored in a way that will not contaminate food, food-preparation areas, and food-contact surfaces.

#### **37.110.511** REGISTRATION REQUIREMENTS

- (1) Registration must follow the requirements provided in 50-50-117, MCA.
- (2) The registrant must provide their name, mailing address, phone number, and e-mail address.
- (3) The registrant must provide a detailed description of cottage food product manufacturing process including equipment and utensils to be used.
- (4) The registrant must dispose of sewage through an approved facility that is:
- (a) a public sewage treatment plant; or
- (b) an individual sewage disposal system that is operated according to law.
- (5) The recipe for each product must be submitted with the application for review and kept on file at the cottage food operation location. Ingredient lists are subject to public disclosure, but recipes are proprietary and are not subject to public disclosure.
- (6) At the time of registration, the registrant must demonstrate that the water for the cottage food operation is either:
- (a) from an approved public water system; or
- (b) meets minimum drinking water standards from a certified laboratory by providing results for total coliform and nitrates from the private well serving the domestic residence that is being registered for the cottage food operation;
- (i) nitrates must be below 10 mg/L from a sample within the last 12 months;
- (ii) total coliforms must be absent from a sample within the last 6 months;
- (iii) failure to meet minimum drinking water standards will result in registration being withheld until samples are provided that meet the minimum nitrate and total coliform standards in this rule.
- (c) Water sampling may also be required by the state or local health authority when cottage food is suspected of being associated with an illness or outbreak.
- (7) A registration fee of \$40.00 must be paid to the county in which the cottage food operation is registered. Once registered, a cottage food operator may sell their registered products anywhere in the state of Montana. The cottage food operation must register again with the local health authority and pay the registration fee if it wishes to change the location of its cottage food operation or produce new products. Recipe changes to an existing approved product that necessitate redetermination as to whether that product constitutes a non-potentially hazardous food or contains a major allergen are new products for the purposes of this rule. While not exhaustive, the following are examples of when a new fee must be paid:
- (a) when a cottage food operator moves to a new house;
- (b) when a cottage food operator changes a recipe in a way that may make the recipe potentially hazardous or adds an allergen, such as switching from a traditional frosting to one that contains cream cheese or adding walnuts to chocolate chip cookies; and
- (c) when a cottage food operator wishes to make a completely new product, such as dried fruit when they had previously registered chocolate chip cookies.



(8) A department-approved certificate of registration will be provided to each new registrant. A certificate of registration must be made available to a local health authority upon request when a cottage food operator is vending to the public.

#### 37.110.513 ENFORCEMENT AND INSPECTIONS

- (1) Cottage food operations will be inspected according to the requirements of 50-50-301(3), MCA.
- (2) Cottage food operators in violation of this subchapter are subject to enforcement action in accordance with Title 50, chapter 50, part 1, MCA.

#### **37.110.514** SAMPLES

(1) A cottage food operator must furnish cottage food product or ingredient samples for analysis upon request of the regulatory authority when the food is suspected of being associated with an illness or outbreak.

#### Montana Codes Annotated

50-50-102. Definitions. Unless the context requires otherwise, in this chapter, the following definitions apply:

- (1) "Consumer" means a person who is a member of the public, takes possession of food, and does not offer the food for resale.
- (2) "Contract cook" means a person who specializes in a home food service and prepares food in an individual's domestic residence only for members of that household and house guests.
- (3) "Cottage food operation" means a person who provides, manufactures, or packages cottage food products only in a kitchen in a registered area of a domestic residence and only for direct sale to a consumer in this state.
- (4) "Cottage food products" means foods that are not potentially hazardous and are processed or packaged in a cottage food operation, including jams, jellies, dried fruit, dry mixes, and baked goods. Other similar foods that are not potentially hazardous may be defined by the department by rule.
- (5) "Department" means the department of public health and human services provided for in 2-15-2201.
- (6) "Direct sale" means a face-to-face purchase or exchange of the cottage food product between the manufacturer or packager of a cottage food product and a consumer or individual purchasing the cottage food product as a gift. The direct sale may not be by consignment or involve shipping or internet sales.
- (7) "Domestic residence" means a single-family house or a unit in a multiunit residential structure, whether rented, leased, or owned by the person in charge of the cottage food operation.
- (8) "Farmer's market" means a farm premises, a food stand owned and operated by a farmer, or an organized market authorized by the appropriate municipal or county authority under 7-21-3301.
- (9) "Food" means an edible substance, beverage, or ingredient used, intended for use, or for sale for human consumption.
- (10) "Local board of health" means a county, city, city-county, or district board of health.
- (11) "Local health officer" means a county, city, city-county, or district health officer, appointed by the local board of health, or the health officer's authorized representative.
- (12) "Meat market" means an operation and buildings or structures in connection with the meat market that are used to process, store, or display meat or meat products for retail sale to the public or for human consumption.
- (13) (a) "Mobile food establishment" means a retail food establishment that serves or sells food from a motor vehicle, a nonmotorized cart, a boat, or other movable vehicle that periodically or continuously changes location and requires a servicing area to accommodate the unit for cleaning, inspection, and maintenance.
- (b) The term does not include:
- (i) a motor vehicle used solely to transport or deliver food by a motorized carrier regulated by the state or the federal government;



- (ii) a cottage food operation transport vehicle; or
- (iii) a concession stand designed to operate as a temporary food establishment.
- (14) "Nonprofit organization" means any organization qualifying as a tax-exempt organization under 26 U.S.C. 501.
- (15) "Person" means an individual, a partnership, a corporation, an association, a cooperative group, the state or a political subdivision of the state, or other entity.
- (16) "Potentially hazardous food" means food that requires time and temperature control for safety to limit toxin formation or the growth of pathogenic microorganisms.
- (17) (a) "Raw agricultural commodity" means any food in its raw, unaltered state, including fruits, vegetables, raw honey, and grains. A raw agricultural commodity may be in a container if putting the commodity in a container does not alter the raw state.
- (b) The term does not include an agricultural commodity that has been altered by being:
- (a) cooked:
- (b) canned;
- (c) preserved, except for drying;
- (d) combined with other food products; or
- (e) peeled, diced, cut, blanched, or otherwise subjected to value-adding procedures.
- (18) "Registered area" means the portion of a domestic residence that has been registered as provided in 50-50-117 and in which food ingredients intended for cottage food products are transported or stored or the domestic residence kitchen where cottage food products are processed, packaged, or stored.
- (19) "Regulatory authority" means the department, the local board of health, the local health officer, or the local sanitarian.
- (20) "Retail" means the provision of food directly to the consumer.
- (21) (a) "Retail food establishment" means an operation, whether mobile or at a temporary or stationary facility or location, that meets one or more of the conditions in subsections (21)(a)(i) and (21)(a)(ii) and that may include a central processing facility that supplies a transportation vehicle or a vending location or satellite feeding location. A retail food establishment:
- (i) stores, processes, packages, serves, or vends food directly to the consumer or otherwise provides food for human consumption at a venue that may include:
- (A) a restaurant;
- (B) a market;
- (C) a satellite or catered feeding location;
- (D) a catering operation if the catering operation provides food directly to a consumer or to a conveyance used to transport people;
- (E) a vending location;
- (F) a conveyance used to transport people;
- (G) an institution; or
- (H) a food bank; and
- (ii) relinquishes possession of food to a consumer directly or indirectly by using either a delivery service, as is done for grocery or restaurant orders, or a common carrier that provides deliveries.
- (b) The term is not dependent on whether consumption is on or off the premises or whether there is a charge for food served to the public.
- (c) The term does not include:
- (i) milk producers' facilities, milk pasteurization facilities, or milk product manufacturing plants;
- (ii) slaughterhouses, meat packing plants, or meat depots;
- (iii) growers or harvesters of raw agricultural commodities;
- (iv) a cottage food operation;
- (v) a person that sells or serves only commercially prepackaged foods that are not potentially hazardous;
- (vi) a food stand that offers raw agricultural commodities;
- (vii) a wholesale food establishment, including those wholesale food establishments that are located on the same premises as a retail food establishment;
- (viii) a kitchen in a domestic residence used for preparing food to sell or serve at a function by a nonprofit



organization as provided in subsection (21)(c)(xiii);

- (ix) custom meat and game animal processors that receive from an owner the remains of a carcass and process those remains for delivery to the owner for the exclusive use in the owner's household by the owner or members of the owner's household, including the owner's family pets, or of the owner's nonpaying guests or employees. For this exemption to apply, the carcass must be kept separate from other meat food products and parts that are to be prepared for sale.
- (x) private, religious, fraternal, youth, patriotic, or civic organizations that serve or sell food to the public over no more than 4 days in a 12-month period;
- (xi) a private organization that serves food only to its members and their guests;
- (xii) a bed and breakfast, a hotel, a motel, a rooming house, a guest ranch, an outfitting and guide facility, a boardinghouse, or a tourist home as defined in 50-51-102 that serves food only to registered guests and day visitors;
- (xiii) a nonprofit organization that operates a temporary food establishment under a permit as provided in 50-50-120;
- (xiv) persons who sell or serve at a farmer's market or a food stand whole shell eggs, hot coffee, hot tea, or other food not meeting the definition of potentially hazardous, as authorized by the appropriate municipal or county authority:
- (xv) a day-care center under 52-2-721(1)(a) or day-care providers who are not subject to licensure under 52-2-721(1)(a):
- (xvi) a private domestic residence that receives catered or home-delivered food;
- (xvii) a contract cook; or
- (xviii) a provider of free samples to the public as a marketing activity if the provider is a licensed wholesale food establishment, a cottage food operation, or a seller at a farmer's market.
- (22) "Temporary food establishment" means a retail food establishment that in a licensing year either:
- (a) operates at a fixed location for no more than 21 days in conjunction with a single event or celebration; or
- (b) uses a fixed menu and operates within a single county at a recurring event or celebration for no more than 45 days.
- (23) (a) "Water hauler" means a person engaged in the business of transporting water for human consumption and use and that is not regulated as a public water supply system as provided in Title 75, chapter 6.
- (b) The term does not include a person engaged in the business of transporting water for human consumption that is used for individual family households and family farms and ranches.

#### 50-50-116. Conditions for cottage food operation exemption from licensure and routine

facility inspection. (1) To acquire the status of not being a retail food establishment, a cottage food operation must meet the conditions in this section and shall register with a local health authority as provided in 50-50-117.

- (2) A cottage food operation shall:
- (a) follow department food standards as provided in rule, including applicable provisions implementing the 2013 United States food and drug administration food code;
- (b) package cottage food products and label the cottage food products prior to sale, including on the label, at a minimum, the following:
- (i) the name, address, city, state, and zip code of the cottage food operation;
- (ii) the name of the cottage food product;
- (iii) the ingredients of the cottage food product, in descending order of predominance by weight;
- (iv) the net quantity, weight, count, or volume of the cottage food product;
- (v) allergen labeling as specified by federal and state labeling requirements;
- (vi) if a nutritional claim is made, an appropriate label if required by federal law; and
- (vii) the following statement, printed in at least the equivalent of 11-point font size in a color that provides a clear contrast to the background and is conspicuously placed on the principal label:



- "Made in a home kitchen that is not subject to retail food establishment regulations or inspections."
- (3) Providing cottage food products by consignment, including at a retail food establishment or through a wholesale establishment, is prohibited.
- (4) Processing or packaging of cottage food products must be in the specific registered area of the domestic residence of the person processing or packaging the cottage food products.
- (5) A cottage food operation may store cottage food products only in the registered area of the primary domestic residence used to produce the cottage food product or temporarily in a motor vehicle used to transport cottage food products.
- (6) (a) A cottage food operation is subject to local health authority or state enforcement action for violations of applicable department regulations.
- (b) Cottage food products may be subject to other state or federal laws or regulations.
- (7) A cottage food operation that meets the requirements in this section is not a retail food establishment or a wholesale food establishment and is not subject to licensure or inspection requirements under Title 50, chapter 57, or this chapter.

# 50-50-121. Requirements for farmer's markets. (1) (a) A person selling food that is not potentially hazardous, including food listed in subsection (2), at a farmer's market is not a retail food establishment.

- (b) A person selling food that is not potentially hazardous or otherwise listed in subsection (2) if selling only at a farmer's market is not required to register as a cottage food operation.
- (2) Foods that are not potentially hazardous or are otherwise eligible to be sold at a farmer's market include:
- (a) whole shell eggs if the whole shell eggs are clean, free of cracks, and stored in clean cartons at a temperature established by the department by rule;
- (b) hot coffee or hot tea if the person selling the hot coffee or hot tea does not provide or include fresh milk or cream;
- (c) raw agricultural commodities; and
- (d) food identified by the department by rule as not being a potentially hazardous food.
- (3) A farmer's market authorized by a municipal or county authority shall keep registration records of all persons and organizations that serve or sell food exempt from licensure at the market, including food that does not meet the definition of potentially hazardous food.
- (4) The registration records must include the name, address, and telephone number of the seller or server as well as the types of products sold or served and the date on which the products were sold or served.
- (5) A farmer's market under this section shall make registration records available upon request to the local health authority.
- (6) Food sold in a farmer's market must, if sold in a container, have a label similar to a label required of a cottage food product under 50-50-116.

# 50-50-301. Health officers and sanitarians to make investigations and inspections --

training requirements. (1) State and local health officers, sanitarians-in-training, and registered sanitarians shall make investigations and inspections of retail food establishments once a year and make reports to the department as required under rules adopted by the department. An inspection may be conducted more often than once a year.

- (2) A person conducting an inspection must be certified and have completed a food safety training program, such as the program administered by the national restaurant association educational foundation or its equivalent.
- (3) (a) A cottage food operation is not subject to inspection under this section unless the state or local health officer is investigating a complaint based on an illness or an outbreak suspected to be directly related to cottage food products.
- (b) A cottage food operation may request an inspection and pay the appropriate costs for that inspection on a voluntary basis.

